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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,140	07/25/2003	David W. Piotrowski	01085.US1	3914

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EXAMINER

HUANG, EVELYN MEI

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

10/627,140

Applicant(s)

PIOTROWSKI ET AL.

Examiner

Evelyn Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 12-25 and 27-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10, 11 and 26 is/are rejected.
- 7) ☒ Claim(s) 8, 9 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

1. Claims 1-36 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-11, 26 in part, drawn to a compound wherein the azabicyclo is of formula I, classified in class 546, subclass 135, and the composition thereof.
 - II. Claims 1-11, 26 in part, drawn to a compound wherein the azabicyclo is of formula II, classified in class 548, subclass various dependent on the species elected, and the composition thereof.
 - III. Claims 1-11, 26 in part, drawn to a compound wherein the azabicyclo is of formula III or IV, classified in class 546, subclass 112, and the composition thereof.
 - IV. Claims 21-25, and claims 1-4, 26 in part, drawn to a compound wherein the azabicyclo is of formula V or VI, classified in class 548, subclass various dependent on the species elected, and the composition thereof.
 - V. Claims 12-20, and claims 1-4, 26 in part, drawn to a compound wherein the azabicyclo is of formula VII, classified in class 548, subclass various dependent on the species elected, and the composition thereof.
 - VI. Claims 27, 31, drawn to a composition comprising multiple active ingredients, classified in class 514, subclass various dependent on the species elected, and the method of use thereof.
 - VII. Claims 28-30, 32-36, drawn to various methods of use, class 514, subclass various dependent on the species elected.

Inventions I-V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

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as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the compound as claimed can be used in multiple processes, such as the treatment of depression, attention deficit disorder, dementia, Parkinson's disease, etc etc.

The patentability of Group VI invention depends on the type and amount of the multiple active ingredients, their interaction, co-action, e.g. synergism etc., which is patentably distinct from the Group I-V compositions containing only a single active ingredient.

The inventions of Groups I-V are structurally, chemically and patentably distinct. They have acquired a separate status in the art as shown by their different classification. A reference anticipating a group I compound would not render obvious the compounds of the other groups. The search is not co-extensive and is burdensome. Since the search required for one group is not required for the other groups, restriction for examination purposes as indicated is proper.

3. During a telephone conversation with Ms. Hoseley on 4-7-2004 a provisional election was made with traverse to prosecute the invention of Group-III, claims 1-11, 26 in part, drawn to a compound wherein the Azabicyclo is of formula III or IV. Affirmation of this election must be made by applicant in replying to this Office action. Claims of Groups I, II, IV-VII are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. The examiner has required restriction between product and process claims, where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

6. Claims 1-7, 10, 26 are objected to because they contain non-elected subject matter. Amending the claims to elected subject matter would obviate the rejection.

Claims 8, 9, 11 are objected to because they are dependent on the objected claims 7, 10 respectively.

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Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 10, 11, 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 1, definition of R3, 'two R3 on adjacent carbon atoms may fuse to form a 6-membered ring to give a 5-6 fused, bicyclic moiety' is unclear as to what kind of 6-membered ring is intended. Saturated or unsaturated? Carbocyclic or heterocyclic? etc. etc. Although benzene is exemplified on page 34, a *full* definition is not found in the specification.

b. Claim 1 recites the broad recitation '10-membered heteroaromatic bicyclic moieties' in the definition of R9, and the claim also recites 'including, but not limited to, quinolinyl or isoquinolinyl'. This can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims.

c. Claim 11, directed to pyrrolyl compound, should be dependent on claim 10, not the recited claim 9, which is a species claim directed to pyrazolyl compounds.

The rejection is applicable to claims dependent on the above claims.

Conclusion

8. The subject matter of the elected Group III compound wherein W is pyrazolyl or pyrrolyl, and the pharmaceutical composition thereof, is allowable.

Piotrowski (US 2003/02079130) discloses an azabicyclic-substituted heteroaryl compound similar to the instant. Piotrowski, however, only teaches that the amido carbonyl is attached to the carbon atom of the 5-membered nitrogen containing heteroaryl, whereas the amido carbonyl is attached to the nitrogen of the pyrrolyl or pyrazolyl in the instant compound. Motivation to modify Piotrowski's compound to arrive at the instant is lacking.

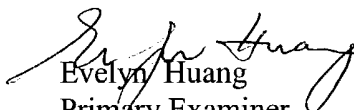
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Walker (US 2003/0153595, the US equivalent of WO 03/029252, PTO-1449) discloses an azabicyclic-substituted heteroaryl compound similar to the instant. Walker, however, only teaches that the amido carbonyl is attached to the carbon atom of the bicyclic nitrogen containing heteroaryl, whereas the amido carbonyl is attached to the nitrogen of pyrrolyl or pyrazolyl fused to a 6-membered ring in the instant compound. Motivation to modify Walker's compound to arrive at the instant is lacking.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Evelyn Huang
Primary Examiner
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